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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,928	03/03/2006	Stephen Peter East	010180.00033	5997
22907 7590 05/12/2008 BANNER & WITCOFF, LTD. 1100 13th STREET, N.W. SUITE 1200 WASHINGTON, DC 20005-4051				
EXAMINER JARRELL, NOBLE E				
ART UNIT		PAPER NUMBER		
1624				
MAIL DATE		DELIVERY MODE		
05/12/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/538,928

**Applicant(s)**

EAST ET AL.

**Examiner**

Noble Jarrell

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 April 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13, 25 and 26 is/are pending in the application.  
4a) Of the above claim(s) 14 and 17-21 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-13, 15, 16, 22, 23, 25 and 26 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/SB/808)  
Paper No(s)/Mail Date 6/13/05  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of group II in the reply filed on 4/8/08 is acknowledged. The traversal is on the ground(s) that group II is not patentably distinct from group III. This is not found persuasive because groups II and III represent different core structures. In group II the core structure is phenyl-C<sub>2</sub>-C(O)N(R<sub>3</sub>)N(R<sub>4</sub>)C(O or S)-pyrrolidine. In group III, the core structure is phenyl-C<sub>2</sub>-C(O)N(R<sub>3</sub>)N(R<sub>4</sub>)C(O or S)-NH<sub>2</sub>, core structure is phenyl-C<sub>2</sub>-C(O)N(R<sub>3</sub>)N(R<sub>4</sub>)C(O or S)-NH-alkyl, or core structure is phenyl-C<sub>2</sub>-C(O)N(R<sub>3</sub>)N(R<sub>4</sub>)C(O or S)-N(alkyl)<sub>2</sub>. Each of these core structures is not considered a co-extensive search with compounds of group II. In addition, the presence of the pyrrolidine changes the classification of the compound. For group II, the compounds are classified in class 548. The compounds of group III are classified in class 564.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 14 and 17-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/8/08.

### *Specification*

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract

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on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The current title "antibacterial agents" gives a reader no guidance to what the compounds actually look like.

#### ***Claim Objections***

5. Claims 1-13, 15-16, 22-23, and 25-26 are objected to because of the following informalities: non-elected subject matter is contained within these claims. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-13, 15-16, 22-23, and 25-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical or veterinary acceptable salt of formula I, does not reasonably provide enablement for the preparation of a solvate or hydrate of formula I. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

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make and/or use the invention commensurate in scope with these claims. Applicants show that a pharmaceutical or veterinary acceptable salt of formula I can be prepared. However, applicants do not show that a solvate or hydrate of a compound of formula I can be prepared. Solvate and hydrate formation is recognized as unpredictable.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Consideration of the relevant factors sufficient to establish a *prima facie* case for lack of enablement is set forth herein below:

(1) *The nature of the invention and (2) the breadth of the claims:*

The claims are drawn to compounds composed of a phenyl-C<sub>2</sub>-C(O)N(R<sub>3</sub>)N(R<sub>4</sub>)C(O or S)-pyrrolidine core and compositions comprising the same.

(3) *The state of the prior art and (4) the predictability or unpredictability of the art:*

Vippagunta et al. (*Advanced Drug Delivery Reviews*, **2001**, 48, 3-26) teach that solvate or hydrate formation, even among a series of related compounds, is

unpredictable (Page 18, section 3.4). Solvate or hydrate formation is considered unpredictable because each individual compound in a genus responds uniquely to solvate or hydrate formation.

*(5) The relative skill of those in the art:*

One of ordinary skill in the art can replicate the synthesis to prepare a compound of example 2 of the specification (page 21-22). The products are all obtained in the form of an oil.

*(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:*

The specification has provided guidance for preparation of a pharmaceutical or veterinary acceptable salt of formula I. However, the specification does not provide guidance for preparation of a solvate or hydrate from a single species of formula I.

*(8) The quantity of experimentation necessary:*

Considering the state of the art as discussed by the references above, particularly with regards to claims 1-13, 15-16, 22-23, and 25-26 the high degree of unpredictability in the art as evidenced herein and the lack of guidance provided in the specification, one skilled in the art would be burdened with undue experimentation to determine which species of compounds make solvates or hydrates commensurate in scope with the specified claims.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-11, 15-16, 22-23, and 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The specification and claims give no guidance as to the specific identity of substituents to be placed on chemical groups for variable  $R_2$  -  $R_5$ .

### ***Conclusion***

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/  
Examiner, Art Unit 1624

**/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624**